



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Commercialization License: The Use of Cysteamine for the Treatment of Pancreatic Cancer, Breast Cancer and Hepatocellular Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, indicates that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization license to practice the inventions embodied in technology family E-219-2013/0, including U.S. patent application 61/814,010 entitled “A Novel Role of Cysteamine in Suppression of Cancer Invasion and Metastasis and Prolonging Survival of Host Through Inhibition of Matrix Metalloproteinases in Human Cancer” [HHS Ref. E-219-2013/0-US-01], Canadian patent application 2,813,514 entitled “Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases” [HHS Ref. E-219-2013/0-CA-02], South Korean patent application 10-2013-43713 entitled “Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases” [HHS Ref. E-219-2013/0-KR-03], Australian patent application 2013205350 entitled “Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases” [HHS Ref. E-219-2013/0-AU-04], and Mexican patent application MX/a/2013/004423 entitled “Use of Cysteamine and Derivatives Thereof to Suppress Tumor Metastases” [HHS Ref. E-219-2013/0-MX-05]; and all related continuing and foreign patents/patent applications for these technology families, to Raptor Pharmaceuticals, Inc. The

patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive commercialization license territory may be worldwide, and the field of use may be limited to:

The treatment of pancreatic cancer, breast cancer and hepatocellular carcinoma (HCC) by using compositions containing cysteamine.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before **INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive commercialization license should be directed to:

David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; E-mail: lambertsond@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Cysteamine is a naturally occurring degradation product of the amino acid cysteine that is most commonly used for the treatment of cystinosis. The inventors on this technology have demonstrated that cysteamine suppresses the activity of matrix metalloproteinases (MMPs), enzymes that have been implicated in tumor invasion and metastasis. Importantly, administration of cysteamine was able to reduce invasion and metastasis in mouse xenograft tumor models for pancreatic cancer, prolonging the survival of the mice while having no adverse side effects. Based on these findings, cysteamine could represent a novel therapeutic treatment of cancer with fewer side-effects than current therapies.

The prospective exclusive commercialization license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404 within thirty (30) days from the date of this published notice.

Complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: September 20, 2013.

Richard U. Rodriguez,
Director,
Division of Technology Development & Transfer,
Office of Technology Transfer,
National Institutes of Health.